

APPENDIX – 1

GENERAL LABELING INFORMATION

I. Indication for Use.

The metal/polymer constrained acetabular liner is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability.

II. Device Description.

The constrained metal/polymer acetabular insert is part of a prosthetic hip joint made of metal such as titanium alloy or cobalt-chromium-molybdenum alloy and ultra-high molecular-weight polyethylene (UHMWPE). The device utilizes a total hip prosthesis head that is captured within an outer UHMWPE acetabular insert with a metal shell. The bipolar type version of the constrained liner generally consists of a femoral head that is captured within a larger polyethylene lined head such that there is articulation both at the head-to-bipolar interface and at the bipolar-to-outer cup interface. The traditional bipolar assembly is itself captured by an outer polyethylene liner that, in turn, is assembled to a standard acetabular shell.

In both styles, the spherical head of the femoral stem is restrained within the acetabular cup device, usually by an UHMWPE ring.

III. Contraindications, Warnings, Precautions, and Potential Adverse Effects.

1. Relative Contraindications

- a. Bone or musculature compromised by disease, infection, or prior implantation that cannot provide adequate support or fixation for the prosthesis.
- b. Any active or suspected infection in or about the hip joint
- c. Skeletal immaturity

2. Warnings

- a. Closed reduction of a dislocation of a constrained hip prosthesis is not possible. Patients should be made aware that treatment of device dislocation would require additional surgery.
- b. Patients should be warned on the impact of excessive loading that can result if the patient is involved in an occupation or activity that includes substantial walking, running, lifting, or excessive muscle loading due to patient weight

causing extreme demands on the constrained insert can result in the failure of the device. Extreme demands on the device may also cause loosening of the acetabular shell.

- c. Alteration of any factory pre-assembled components can result in improper function of the retaining mechanisms, and failure of the device. Discard or return any constrained insert if the retaining mechanism appears damaged or mishandled.
- d. Improper alignment of the acetabular insert within the acetabular shell prior to impaction may result in damage to the locking mechanism, or improper seating of the constrained acetabular insert.
- e. Bending, contouring, or modifying this device may adversely affect the implant potentially leading to early implant failure.
- f. Do not use steam autoclaving for resterilization of the **UHMWPE** liner, as it may result in serious deformation and **material** deterioration,
- g. Do not combine components from different manufacturers. This may lead to premature wear or failure of the device.

3. Precautions

- a. **Careful** selection of components and familiarity with all aspects of the surgical technique are important to the success of the surgery.
- b. An implant should be handles carefully to avoid damage that could compromise the mechanical integrity of the device and cause early failure or loosening.
- c. Inspect implants for nicks, scratches, or other defects that may cause failure of the implant.
- d. To prevent contamination of the prosthesis, keep **free** of lint and powders. Do not open the package until surgery. Do not place the implant in contact with prepared bone surfaces before the final decision to implant has been made.
- e. An implant should never be reused. Any implant once assembled and Disassembled should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure.
- f. The wear rate of prosthetic contact surfaces is greatly accelerated if loose

fragments of bone cement become detached and act as an abrasive in the bearing surfaces. When using bone cement, care should be taken to remove all excess cement from the periphery of the implant.

- g. If a metal acetabular shell is affixed without bone cement, an additional method of initial fixation (e.g. bone screws, spikes, screw threads, fins, etc.) should be utilized to assure early stabilization of the cup.

4. Potential Adverse Effects

- a. Infection
- b. Pain
- c. Loosening, wear, or mechanical failure of the prosthetic components
- d. Dislocation of the hip prosthesis requiring additional surgery
- e. Localized progressive bone **resorption**, (osteolysis)
- f. Nerve impingement or damage, vascular disorders (including thrombus)
- g.** Heterotopic bone formation
- h. Sensitivity to implant materials
- i. Gastrointestinal and/or genitourinary complications
- j.** Pulmonary embolism
- k. Death
- l. Myocardial infarction

IV. Sterility and Handling

- 1. Acetabular components are supplied pre-sterilized by a minimum of 25 kGy of gamma irradiation.
- 2. Do Not Re-Sterilize - For Single Use Only
- 3. Components are sterile unless the package is damaged or opened. Use by date - if applicable.
- 4. **CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.**